

Amendments to the Claims

The following listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Withdrawn) A method of making 2-butyl-3-[2'-(triphenylmethyltetrazol-5-yl)-biphenyl-4-yl methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one comprising the step of reacting 2-butyl-1,3-diaza-spiro[4.4]non-1-ene-4-one and 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole in the presence of a phase transfer catalyst in a reaction system comprising first and second phases.
2. (Withdrawn) The method of claim 1 wherein the first phase comprises an aromatic or aliphatic hydrocarbon and the second phase comprises water.
3. (Withdrawn) The method of claim 2 wherein, prior to reaction, the 2-butyl-1,3-diazaspiro[4.4]non-1-ene-4-one is in solution in aqueous base.
4. (Withdrawn) The method of claim 3 wherein the aqueous base is selected from the group consisting of KOH, NaOH and LiOH.
5. (Withdrawn) The method of claim 4 wherein the aqueous base is aqueous KOH.
6. (Withdrawn) The method of claim 2 wherein, prior to reaction, the 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole is in solution in an aromatic or aliphatic hydrocarbon.
7. (Withdrawn) The method of claim 6 wherein the 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole is in solution in an aromatic hydrocarbon that is toluene.
8. (Withdrawn) The method of claim 2 wherein the 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole is in solution in an aliphatic hydrocarbon.
9. (Withdrawn) The method of claim 1 wherein the phase transfer catalyst is a quaternary ammonium compound.
10. (Withdrawn) The method of claim 9 wherein the quaternary ammonium compound is tetrabutyl ammonium hydrogensulfate.
11. (Currently amended) A method for making irbesartan comprising the steps of:
 - a) combining 2-butyl-1,3-diaza-spiro[4.4]non-1-ene-4-one and 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole in the presence of a phase transfer catalyst in a reaction system comprising first organic and second aqueous phases;
 - b) heating the combination to a temperature of about 20° C and about 95° C;
 - c) separating the first organic and second aqueous phases;

d) removing solvent from the ~~first~~ organic phase to obtain a residue of 2-butyl-3-[2'-(triphenylmethyltetrazol-5-yl)-biphenyl-4-yl methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one;

e) dissolving the residue in a water-miscible solvent in the presence of a mineral acid to form a solution; ~~providing a mineral or sulfuric acid acidified solution of the residue in a water-miscible solvent~~;

f) basifying the solution ~~in water-miscible solvent~~ with an inorganic base;

g) removing the water-miscible solvent from the solution to obtain a precipitate of trityl alcohol;

h) separating the precipitated trityl alcohol from the solution ~~so formed~~; and

i) recovering irbesartan from the solution.

12. (Original) The method of claim 11 wherein the water miscible solvent is acetone.

13. (Currently amended) The method of claim 11 wherein the solution is basified ~~basification is with an inorganic base~~ to a pH of about 8 to about 12.

14. (Currently amended) The method of claim 13 wherein the solution is basified ~~basification with inorganic base is~~ to a pH of about 9 to about 10.5.

15. (Currently amended) In a method of making irbesartan, the step of combining, in the presence of a phase transfer catalyst, a solution of 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole in a first solvent that is an aromatic or aliphatic hydrocarbon and a solution of 2-butyl-1,3-diazaspiro[4.4]non-1-ene-4-one in a second solvent comprising water and an inorganic base, whereby ~~first (organic)~~ and ~~second (aqueous)~~ phases are formed.

16. (Previously presented) The method of claim 15 wherein the first solvent is the aromatic hydrocarbon toluene.

17. (Original) The method of claim 15 wherein the phase transfer catalyst is tetrabutylammonium hydrogensulfate.

18. (Original) The method of claim 15 wherein the inorganic base is KOH.

19. (New) The method of claim 11, wherein the phase transfer catalyst is a quaternary ammonium compound or a phosphonium compound.

20. (New) The method of claim 11, wherein the phase transfer catalyst is tetrabutylammonium hydrogensulfate.